K070627

page 1 of 2

AUG - 2 2007

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Ciden Technologies, LLC
360 Cold Spring Avenue
West Springfield, MA 01089
Telephone: (413) 747-7086
Fax: (413) 747-9721
Contact person: Damon D'Amico, President

Date of Summary: May 30, 2007

Device Names: Trade Name: Opaciden® Solution
Common Name: High level disinfectant
Classification Name: Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate device is CIDEX® OPA Solution (K030004), manufactured by Advanced Sterilization Products, determined to be substantially equivalent to a legally marketed (preAmendment) device on February 27, 2003.

Device Description: Opaciden Solution is a clear, pale blue liquid with a pH of 7.5. It contains 0.60% *ortho*-Phthalaldehyde in an aqueous base containing buffers, chelating agents and a corrosion inhibitor. It is stable at 15-30° C (59-86° F) for its labeled shelf life. The product may be used or reused (up to 14 days) for manual or automated reprocessing, according to the Directions for Use. Opaciden Solution must be used at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with the immersion time and temperature specified for the disinfection method.

Intended Use: Opaciden Solution is a high level disinfectant for reprocessing heat-sensitive medical devices for which sterilization is not suitable, and when used according to the Directions for Use. Opaciden may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20° C (68° F), for a reuse period not to exceed 14 days. Opaciden may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25° C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25° C (77° F), for a reuse period not to exceed 14 days.

K070627
page 2 of 2

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The indications for use of Opaciden Solution are identical to those of the predicate device. The chemical formulation of Opaciden is very similar to that of the predicate device. There are no substantial technical or functional differences between the two products. Based on this information and the results of performance testing, it is expected that Opaciden will be compatible with all automated endoscope reprocessors currently validated for use with Cidex OPA.

Performance Data: Opaciden Solution has been tested, in both the manual and automated reprocessing modes, in accordance with applicable sections of the January 2000, FDA guidance for these products. All test results were acceptable and demonstrated performance in accordance with the product labeling, as well as substantial equivalence to the predicate device.

Conclusion: The information and data provided in this 510(k) Notification establish that Opaciden Solution is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2007

Ciden Technologies, LLC
C/O Ms. Lisa S. Jones
Regulatory Affairs Consultant
Devices for the Future
540 College Street
Bellaire, Texas 77401-5010

Re: K070627
Trade/Device Name: Opaciden Solution
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: July 20, 2007
Received: July 23, 2007

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 7

Indications for Use

510(k) Number: K070627

Device Name: Opaciden Solution

Indications for Use: Opaciden Solution is a high level disinfectant for reprocessing heat sensitive semi-critical medical devices for which sterilization is not suitable, and when used according to the Directions for Use. Opaciden may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by Opaciden OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20° C (68° F), for a reuse period not to exceed 14 days. Opaciden may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25° C), at or above its Minimum Recommended Concentration (MRC), as determined by Opaciden OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25° C (77° F), for a reuse period not to exceed 14 days.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K070627